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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,137	06/26/2003	Soheil Shams		6733

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EXAMINER	
BRUSCA, JOHN S	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
01/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/609,137	SHAMS, SOHEIL	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-20,22-39 and 41-81* is/are pending in the application.

4a) Of the above claim(s) *5,6,24,25,43,44,60,68 and 76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7-20,22,23,28-39,41,42,47-59,61-67,70-75 and 78-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *26, 27, 45, 46, 69, and 77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 3-20, 22-39, and 41-81 are pending.

Claims 5, 6, 24, 25, 43, 44, 60, 68, and 76 are withdrawn

Claims 1, 3, 4, 7-20, 22, 23, 28-39, 41, 42, 47-59, 61-67, 70-75, and 78-81 are rejected.

Claims 26, 27, 45, 46, 69, and 77 are objected to.

Claim Rejections - 35 USC § 101

2. The rejection of claims 1, 3, 4, 7-20, 22, 23, 26-39, 41, 42, 45-59, 61-67, 69-75, and 77-81 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter for lack of a requirement of a tangible result in the Office action mailed 03 April 2008 is withdrawn in view of the amendment to the claims filed 06 October 2008.

3. The rejection of claims 20, 22, 23, 26-39, 41, 42, 45-57, 66, 67, 69-75, and 77-81 under 35 U.S.C. 101 because the claimed invention is drawn to non-statutory subject matter for having an embodiment that is information on a carrier wave in the Office action mailed 03 April 2008 is withdrawn because upon further consideration claims 20, 22, 23, 26-38, 66, and 67-73 are drawn to a computer apparatus rather than carrier waves, and further because of the applicants arguments field 06 October 2008 that the claimed subject matter of claims 39, 41, 42, 45-57, 74, 75, and 77-81 do not include embodiments that are carrier waves, but instead are physical objects encoded with computer programs.

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 4, 7-19, 58, 59, and 61-65 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter.

Claims 1, 3, 4, 7-19, 58, 59, and 61-65 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

The claimed subject matter is not limited to a particular apparatus or machine. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter (In re Grams 12 USPQ2d 1824 Fed. Cir. 1989). Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. The applicants are cautioned against introduction of new matter in an amendment.

Claim Rejections - 35 USC § 102

5. The rejection of claims 1, 3, 4, 9-17, 58, 59, and 62-65 under 35 U.S.C. 102(b) as being anticipated by Caron et al. in the Office action mailed 03 April 2008 is withdrawn in view of the amendment to the claims filed 06 October 2008.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 4, 11, 12, 58, 59, and 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimomura et al. (J. Clin. Invest. Vol. 99, pages 838-845 (1997)).

The claims are drawn to a method of determining the start and stop position for an exon, aligning gene expression data of the exon to a chromosomal map thereby creating an expression map. In some embodiments expression of genes under two different conditions are mapped to chromosomal positions and compared.

Shimomura et al. shows in the introduction on pages 838-839 that the SREBP-1 gene is expressed in two alternative spliced forms. Figure 1 shows the two forms and the exon 1 sequence and map relative to the two alternatively spliced forms. Shimomura et al. quantitates the levels of the two alternative spliced mRNAs in figures 3-7. Shimomura et al. shows that the relative amounts of the two alternative spliced mRNAs vary if the cells are treated with lovastatin plus Colestipol (figure 5), and sterols (Table II), dexamethasone, insulin, and a phosphodiesterase inhibitor relative to untreated controls (figure 6).

Claim Rejections - 35 USC § 103

8. The rejection of claims 1, 18-20, 22, 23, 28-39, 41, 42, 47-57, 66, 67, 70-75, and 78-81 rejected under 35 U.S.C. 103(a) as being unpatentable over Caron et al. in view of Kanehisa et al. in the Office action mailed 03 April 2008 is withdrawn in view of the amendment to the claims filed 06 October 2008.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 11, 19, 20, 22, 23, 30, 31, 33, 38, 39, 41, 42, 49, 50, 57, 66, 67, 70-72, 74, 75, and 78-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. in view of Kanehisa et al. (Nucl. Acids Res. Vol. 28, pages 27-30 (2000)).

The claims are drawn to a method of determining the start and stop position for an exon, aligning gene expression data of the exon to a chromosomal map thereby creating an expression map. In some embodiments the claims are drawn to computers and programs that execute the method. In some embodiments expression of genes under two different conditions are mapped to chromosomal positions and compared. In some embodiments the maps are of different genomes.

Shimomura et al. shows in the introduction on pages 838-839 that the SREBP-1 gene is expressed in two alternative spliced forms. Figure 1 shows the two forms and the exon 1 sequence and map relative to the two alternatively spliced forms. Shimomura et al. quantitates the levels of the two alternative spliced mRNAs in figures 3-7. Shimomura et al. shows that the relative amounts of the two alternative spliced mRNAs vary if the cells are treated with lovastatin plus Colestipol (figure 5), and sterols (Table II), dexamethasone, insulin, and a phosphodiesterase inhibitor relative to untreated controls (figure 6).

Shimomura et al. does not explicitly show computers and programs that execute their method. Shimomura et al. does not show comparison of expression profiles of different genomes.

Kanehisa et al. describe a knowledge base termed KEGG in the abstract and throughout that comprises genomic information including genomic maps and gene expression profiles. Kanehisa et al. states on page 27 that their knowledge base uses computerized tools and software to facilitate the analysis depicted in figure 1. Kanehisa et al. shows on page 28 that their system comprises gene expression profiles that allow the user to detect co-regulated genes that are

clustered on a chromosome. Table 1 shows that KEGG has 23 complete genome maps and four sets of expression maps. Kanehisa et al. shows comparison of orthologs and genome-genome comparisons on page 29.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of generating expression map comparisons of Shimomura et al. by use of data of multiple genomes because Kanehisa et al. shows databases and methods of comparing data of multiple genomes to compare orthologs. It would have been further obvious to automate the procedures of Shimomura et al. because Kanehisa et al. shows that similar collections of expression maps can be analyzed by computers and programs, and because automation of a manual activity is recognized as obvious, as noted in the MPEP at section 2144.04:

III. AUTOMATING A MANUAL ACTIVITY

In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958) (Appellant argued that claims to a permanent mold casting apparatus for molding trunk pistons were allowable over the prior art because the claimed invention combined "old permanent-mold structures together with a timer and solenoid which automatically actuates the known pressure valve system to release the inner core after a predetermined time has elapsed." The court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.).

11. Claims 1, 4, 9, 10, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. in view of Walker et al. (Am. J. Physiol. Cell Physiol. Vol. 280, pages C1184-C1192(2001))

The claims are drawn to a method of determining the start and stop position for an exon, aligning gene expression data of the exon to a chromosomal map thereby creating an expression map. In some embodiments the method is repeated to determine expression of at least two genes.

Shimomura et al. shows in the introduction on pages 838-839 that the SREBP-1 gene is expressed in two alternative spliced forms. Figure 1 shows the two forms and the exon 1 sequence and map relative to the two alternatively spliced forms. Shimomura et al. quantitates the levels of the two alternative spliced mRNAs in figures 3-7. Shimomura et al. shows that the relative amounts of the two alternative spliced mRNAs vary if the cells are treated with lovastatin plus Colestipol (figure 5), and sterols (Table II), dexamethasone, insulin, and a phosphodiesterase inhibitor relative to untreated controls (figure 6).

Shimomura et al. does not show comparison of expression of two genes at the exon level.

Walker et al. shows determination of alternative splicing and quantitation of the alternative forms of mRNA for two transient receptor potential (TRP) genes (TRP4 and TRP7) at the exon level (see figures 2, 5,and 6). Walker et al. shows that different splice variants are expressed at different levels in different murine and canine tissues in figures 5 and 6.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Shimomura et al. to analyze additional genes for expression at the exon level because Walker et al. shows the existence of related genes that are alternatively spliced, and that exon level analysis is helpful to determine which alternatively spliced mRNA is expressed in different tissues.

12. Claims 1, 11, 13-18, 58, 62, 63, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. in view of Caron et al. (Science Vol. 291, pages 1289-1292 (2001)).

The claims are drawn to a method of determining the start and stop position for an exon, aligning gene expression data of the exon to a chromosomal map thereby creating an expression map. In some embodiments the measured genes are clustered, the measured genes are in groups, and entire chromosomes and different chromosomes are mapped.

Shimomura et al. shows in the introduction on pages 838-839 that the SREBP-1 gene is expressed in two alternative spliced forms. Figure 1 shows the two forms and the exon 1 sequence and map relative to the two alternatively spliced forms. Shimomura et al. quantitates the levels of the two alternative spliced mRNAs in figures 3-7. Shimomura et al. shows that the relative amounts of the two alternative spliced mRNAs vary if the cells are treated with lovastatin plus Colestipol (figure 5), and sterols (Table II), dexamethasone, insulin, and a phosphodiesterase inhibitor relative to untreated controls (figure 6).

Shimomura et al. does not explicitly show the measured genes are clustered, the measured genes are in groups, and mapping of entire chromosomes and different chromosomes.

Caron et al. details results from a complete human transcriptome map of 23 human chromosomes (Fig. 3). Caron et al. shows on page 1289 that SAGE expression data was used (which is derived from processed cDNA transcripts, known in the art to consist of exons, as shown in page 3 of the supplemental material). Caron et al. shows a portion of the complete transcriptome map of chromosome 11 in figure 1 in which the expression profiles of eight different cell types are indicated. Caron et al. determines clusters of regions of increased gene

expression (termed RIDGEs) on page 1290-1292. Caron et al. shows tissue specific gene expression can be determined by their data in figure 1, and tumor specific gene expression data in figure 2. Caron et al. provides guidance on page 1292 to use the Human Transcriptome Map to identify candidate cancer associated genes, and to relate RIDGES to nuclear substructures such as nuclear speckles, PML bodies, and coiled bodies.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of exon expression analysis of Shimonura et al. by extending the analysis to other genes and chromosomes because Caron et al. presents SAGE expression level data of the entire human transcriptome and further provides guidance to use the data to study cancer associated genes, tissue specific genes, and correlation of RIDGES with nuclear structures.

13. Claims 20, 23, 28-32, 42, and 47-51 rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. in view of Kanehisa et al. as applied to claims 1, 11, 19, 20, 22, 23, 30, 31, 33, 38, 39, 41, 42, 49, 50, 57, 66, 67, 70-72, 74, 75, and 78-80 above, and further in view of Walker et al.

The claims are drawn to computers and computer programs that execute a method of determining the start and stop position for an exon, aligning gene expression data of the exon to a chromosomal map thereby creating an expression map. In some embodiments the method is repeated to determine expression of at least two genes.

Shimomura et al. in view of Kanehisa et al. as applied to claims 1, 11, 19, 20, 22, 23, 30, 31, 33, 38, 39, 41, 42, 49, 50, 57, 66, 67, 70-72, 74, 75, and 78-80 above does not show a method that is repeated to determine expression of at least two genes.

Walker et al. shows determination of alternative splicing and quantitation of the alternative forms of mRNA for two transient receptor potential (TRP) genes (TRP4 and TRP7) at the exon level (see figures 2, 5,and 6). Walker et al. shows that different splice variants are expressed at different levels in different murine and canine tissues in figures 5 and 6.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Shimomura et al. in view of Kanehisa et al. as applied to claims 1, 11, 19, 20, 22, 23, 30, 31, 33, 38, 39, 41, 42, 49, 50, 57, 66, 67, 70-72, 74, 75, and 78-80 above to analyze additional genes for expression at the exon level because Walker et al. shows the existence of related genes that are alternatively spliced, and that exon level analysis is helpful to determine which alternatively spliced mRNA is expressed in different tissues.

14. Claims 20, 23, 33-37, 39, 52-56, 66, 72-74, 78, 80, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. in view of Kanehisa et al. as applied to claims 1, 11, 19, 20, 22, 23, 30, 31, 33, 38, 39, 41, 42, 49, 50, 57, 66, 67, 70-72, 74, 75, and 78-80 above, and further in view of Caron et al.

The claims are drawn to a method of determining the start and stop position for an exon, aligning gene expression data of the exon to a chromosomal map thereby creating an expression map. In some embodiments the measured genes are clustered, the measured genes are in groups, and entire chromosomes and different chromosomes are mapped.

Shimomura et al. in view of Kanehisa et al. as applied to claims 1, 11, 19, 20, 22, 23, 30, 31, 33, 38, 39, 41, 42, 49, 50, 57, 66, 67, 70-72, 74, 75, and 78-80 above does not show

measured genes that are clustered, measured genes in groups, and mapping of entire chromosomes and different chromosomes.

Caron et al. details results from a complete human transcriptome map of 23 human chromosomes (Fig. 3). Caron et al. shows on page 1289 that SAGE expression data was used (which is derived from processed cDNA transcripts, known in the art to consist of exons, as shown in page 3 of the supplemental material). Caron et al. shows a portion of the complete transcriptome map of chromosome 11 in figure 1 in which the expression profiles of eight different cell types are indicated. Caron et al. determines clusters of regions of increased gene expression (termed RIDGEs) on page 1290-1292. Caron et al. shows tissue specific gene expression can be determined by their data in figure 1, and tumor specific gene expression data in figure 2. Caron et al. provides guidance on page 1292 to use the Human Transcriptome Map to identify candidate cancer associated genes, and to relate RIDGES to nuclear substructures such as nuclear speckles, PML bodies, and coiled bodies.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of exon expression analysis of Shimomura et al. in view of Kanehisa et al. as applied to claims 1, 11, 19, 20, 22, 23, 30, 31, 33, 38, 39, 41, 42, 49, 50, 57, 66, 67, 70-72, 74, 75, and 78-80 above by extending the analysis to other genes and chromosomes because Caron et al. presents SAGE expression level data of the entire human transcriptome and further provides guidance to use the data to study cancer associated genes, tissue specific genes, and correlation of RIDGES with nuclear structures.

Allowable Subject Matter

15. Claims 7, 8, 26, 27, 45, 46, 61, 69, and 77 are not anticipated or obvious over the prior art.

16. Claims 26, 27, 45, 46, 69, and 77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John S. Brusca/
Primary Examiner, Art Unit 1631

jsb